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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,496	08/29/2001	Jill Tolle	A33944 (065855.0127)	6244

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BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
FRENEL, VANEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,496	TOLLE ET AL.	
	Examiner	Art Unit	
	Vanel Frenel	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1152002, 3172003* 11/8/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Application filed on 08/29/01. Claims 1-35 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portwood et al (6,305,377) in view of Edelson et al (5,737,539).

(A) As per claim 1, Portwood discloses a method for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest, comprising the steps of:

(a) receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including de-identified patient identification number, dosage, and prescription product information (See Portwood, Col.2, lines 60-67 to Col.3, line 22; Col.8, lines 14-65);

(d) for each de-identified patient, comparing dosage and prescription

product information contained in a first extracted historical de-identified patient record with dosage and prescription product information contained in a second extracted historical de-identified patient record (See Portwood, Col.8, lines 14-65); and

(e) for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product (See Portwood, Col.11, lines 8-21).

Portwood does not explicitly disclose (b) receiving user-specified information defining a subset of the historical de-identified patient prescription records;

(c) extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset.

However, these features are known in the art, as evidenced by Edelson. In particular, Edelson suggests (b) receiving user-specified information defining a subset of the historical de-identified patient prescription records (See Edelson, Col.39, lines 42-67 to Col.40, line 55);

(c) extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset (See Edelson, Col.39, lines 42-67 to Col.40, line 55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Edelson within the system of Portwood with the motivation of providing a) electronic posting means to select and capture in said prescription: i) a patient identifier; ii) a prescribed drug; iii) a dosage for said prescribed

drug; and b) a patient-condition treatment specification procedure; whereby in creating said prescription said prescriber specifies a patient condition for treatment by said prescriber drug (See Edelson, Col.4, lines 31-38).

(B) As per claim 2, Portwood discloses the method wherein the step of receiving user-specified information further comprises receiving information concerning an observation period (See Portwood, Col.10, lines 48-67 to Col.11, line 20).

(C) As per claim 3, Portwood discloses the method wherein the step of extracting de-identified patient prescription records further comprises discarding a historical de-identified patient prescription record having an eligibility of shorter duration than the observation period (See Portwood, Col.11, lines 8-67 to Col.12, line 67).

(D) As per claim 4, Edelson discloses the method wherein the step of categorizing prescriptions further comprises categorizing a prescription of a product as a new therapy start when a de-identified patient has had no other prescriptions in a therapeutic area to which the product pertains (See Edelson, Col.36, lines 1-42).

The motivation for combining the respective teachings of Portwood and Edelson are as discussed in the rejection of claim 1 above, and incorporated herein.

(E) As per claim 5, Edelson discloses the method wherein the step of categorizing prescriptions further comprises categorizing a prescription as a therapy switch when a

de-identified patient has had no other prescriptions of the product, and when the de-identified patient has had a prescription of a second product within a therapeutic area to which the product pertains that was not prescribed on the same day as the prescription (See Edelson, Col.36, lines 1-67).

The motivation for combining the respective teachings of Portwood and Edelson are as discussed in the rejection of claim 1 above, and incorporated herein.

(F) As per claim 6, Edelson discloses the method wherein step of categorizing prescriptions further comprises categorizing a prescription as an add-on therapy when the de-identified patient had no other prescriptions for the product but had a prescription for a second product within the therapeutic area to which the product pertains that was prescribed on the same day (See Edelson, Col.26, lines 19-28).

The motivation for combining the respective teachings of Portwood and Edelson are as discussed in the rejection of claim 1 above, and incorporated herein.

(G) As per claim 7, Portwood discloses the method wherein the step of categorizing prescriptions further comprises categorizing a prescription as a titration decrease when a de-identified patient has previously had a prescription for the product at a higher dosage (See Portwood, Col.13, lines 1-31).

(H) As per claim 8, Portwood discloses the method wherein the step of categorizing prescriptions further comprises categorizing a prescription as a titration increase when a

de-identified patient has previously had a prescription for the product at a lower dosage (See Portwood, Col.14, lines 42-67).

(I) As per claim 9, Portwood discloses the method wherein the step of categorizing prescriptions further comprises categorizing a prescription as continued therapy when a de-identified patient has previously had a prescription for the product at the same dosage (See Portwood, Col.14, lines 10-67).

(J) As per claim 10, Portwood discloses a method for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest comprising the steps of:

(a) receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including de-identified patient identification number, prescription product information, date dispensed, dosage, number of days supplied, and receiving a plurality of historical de-identified patient prescription refill information (See Portwood, Col.2, lines 60-67 to Col.3, line 22; Col.8, lines 14-65);

(d) for each de-identified patient, comparing dosage and prescription product information contained in a first extracted historical de-identified patient record with dosage and prescription product information contained in a second extracted historical de-identified patient record (See Portwood, Col.8, lines 14-65);

(e) for each comparison made in step (d), categorizing a prescription

based on a change in dosage or prescription product (See Portwood, Col.11, lines 8-21);

(f) extracting at least one relevant historical de-identified patient prescription record from the prescriptions categorized at step (e) based on the refill information (See Portwood, Col.8, lines 54-65);

(g) for each de-identified patient, determining a refill due date based on the dosage and the number of days supplied for a first prescription (See Portwood, Col. 17, lines 1-50);

(h) for each de-identified patient, comparing the refill due date of the first prescription with the date dispensed for a second prescription (See Portwood, Col.17, lines 1-50); and

(i) for each comparison made in step (h), categorizing the de-identified patient based on the duration between the refill due date of the first prescription and the date dispensed for the second prescription (See Portwood, Col.8, lines 37-67).

Portwood does not explicitly disclose that the method having (b) receiving user – specified information defining a subset of the historical de-identified patient prescription records;

(c) extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset.

However, these features are known in the art, as evidenced by Edelson. In particular, Edelson suggests the method having (b) receiving user –specified information defining a subset of the historical de-identified patient prescription records (See Edelson, Col.39, lines 42-67 to Col.40, line 55);

(c) extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset (See Edelson, Col.39, lines 42-67 to Col.40, line 55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Edelson within the system of Portwood with the motivation of providing a) electronic posting means to select and capture in said prescription: i) a patient identifier; ii) a prescribed drug; iii) a dosage for said prescribed drug; and b) a patient-condition treatment specification procedure; whereby in creating said prescription said prescriber specifies a patient condition for treatment by said prescriber drug (See Edelson, Col.4, lines 31-38).

(K) As per claim 12, Portwood discloses the method further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a de-identified patient having more than one physician during the observation period (See Portwood, Col.7, lines 1-50).

(L) As per claim 13, Portwood discloses the method wherein the step of extracting de-identified patient prescription records based on refill information further comprises

discarding a historical de-identified patient prescription record not having a refill due within the observation period (See Portwood Col.8, lines 1-65).

(M) As per claim 16, Edelson discloses the method further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a prescription categorized as a therapy switch (See Edelson, Col.36, lines 43-67).

(N) As per claim 18, Edelson discloses the method further comprising a step of discarding, after step (e) a historical de-identified patient prescription record for a prescription categorized as a titration decrease (The Examiner interprets any chemical substance such as "TAGAMET" which can be dissolved in water may contain titration in it whether to increase or decrease the solution as a means of concentration See Edelson Col.5, lines 40-56).

The motivation for combining the respective teachings of Portwood and Edelson are as discussed in the rejection of claims 1 and 10 above, and incorporated herein.

(O) As per claim 20, Edelson discloses the method further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a prescription categorized as a titration increase (The Examiner interprets any chemical substance such as "TAGAMET" which can be dissolved in water may enable titration. whether to increase or decrease the solution as a means of concentration See Edelson Col.5, lines 40-56).

The motivation for combining the respective teachings of Portwood and Edelson are as discussed in the rejection of claims 1 and 10 above, and incorporated herein.

(P) As per claim 21, Portwood discloses the method wherein the step of categorizing the de-identified patient based on the duration between the due date of the first prescription and the fill date of the second prescription further comprises categorizing the de-identified patient as persistent if the duration is shorter than a predetermined number of days (See Portwood, Col.12, lines 56-67).

(Q) As per claim 22, Portwood discloses the method wherein the step of categorizing the de-identified patient based on the duration between the due date of the first prescription and the fill date of the second prescription further comprises categorizing the de-identified patient as non-persistent if the duration is greater than a predetermined number of days (See Portwood, Col.13, lines 1-31; Col.15, lines 1-36).

(R) As per claim 23, Portwood discloses the method further comprising a step of determining, after step (i), the total number of persistent de-identified patients and the total number of non-persistent de-identified patients for each physician (See Portwood Col.7, lines 1-50).

(S) As per claim 24, Portwood discloses the method further comprising a step of calculating, after the step of determining the total number of persistent de-identified

patients and the total number of non-persistent de-identified patients for each physician, persistence of the physician by dividing the total number of persistent de-identified patients by the total number of de-identified patients for each physician (See Portwood Col.9, lines 1-55).

(T) As per claim 25, Portwood discloses a system for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest, comprising:

(a) a mass storage device for storing a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including a de-identified patient identification number, dosage, number of days supplied and prescription product information, dosage, fill date, and number of days supplied (See Portwood, Col.2, lines 60-67 to Col.3, line 22; Col.8, lines 14-65);

(c) a prescription categorizer, coupled to the input device, configured to compare the dosage and the prescription product infonuation contained in a first historical de-identified patient prescription record with the dosage and prescription product information contained in a second historical de-identified patient prescription record, and to categorize a prescription based on a change in dosage or prescription product (See Portwood, Col.8, lines 14-65); and

(d) a persistence calculator, coupled to the prescription categorizer, configured to determine the due date of a first prescription based on the dosage and the

number of days supplied, to compare the due date of the first prescription with the fill date of a second prescription, and to categorize the de-identified patient based on the duration between the due date of the first prescription and the fill date of the second prescription (See Portwood, Col.8, lines 37-67).

Portwood does not explicitly disclose that the system having (b) an input device, coupled to the mass storage device, for receiving user-specified information which defines a subset of the plurality of historical de- identified patient prescription records.

However, these features are known in the art, as evidenced by Edelson. In particular, Edelson suggests that the system having (b) an input device, coupled to the mass storage device, for receiving user-specified information which defines a subset of the plurality of historical de- identified patient prescription records (See Edelson, Col.39, lines 42-67 to Col.40, line 55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Edelson within the system of Portwood with the motivation of providing a) electronic posting means to select and capture in said prescription: i) a patient identifier; ii) a prescribed drug; iii) a dosage for said prescribed drug; and b) a patient-condition treatment specification procedure; whereby in creating said prescription said prescriber specifies a patient condition for treatment by said prescriber drug (See Edelson, Col.4, lines 31-38).

(U) As per claim 32, Portwood discloses the system of claim 25, wherein the persistence calculator is further configured to categorize the de-identified patient as

persistent if the duration between the due date of the first prescription and the fill date of the second prescription is shorter than a predetermined number of days (See Portwood, Col.12, lines 56-67).

(V) As per claim 33, Portwood discloses the system wherein the persistence calculator is further configured to categorize the de-identified patient as non-persistent if the duration between the due date of the first prescription and the fill date of the second prescription is greater than a predetermined number of days (See Portwood, Col.13, lines 1-31; Col.15, lines 1-36).

(W) As per claim 34, Portwood discloses the system wherein the persistence calculator is further configured to determine the total number of persistent de-identified patients and the total number of non-persistent de-identified patients for each physician (See Portwood, Col.10, lines 9-67).

(X) As per claim 35, Portwood discloses the system wherein the persistence calculator is further configured to determine the persistence of the physician by dividing the total number of persistent de-identified patients by the total number of de-identified patients for each physician (See Portwood, Col.10, lines 9-67).

(Y) Claims 11, 14-15, 17, 19, and 26-31 recite the underlying process of the elements of claims 2,4-9, and respectively. As the various elements of claims 2, 4-9

have shown to be either disclosed by or obvious in view of the collective teachings of Portwood and Edelson, it is readily apparent that the apparatus disclosed by the applied prior art performs the underlying functions. As such, the limitations recited in claims 11, 14-15, 17, 18, and 26-31, and incorporated herein.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not the applied art teaches computer implemented patient medication review system and process for the managed care, health care and/or pharmacy industry (6,014,631) and system for medication dispensing and integrated data management (2002/0032582).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 571-272-6769. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

V.F
V.F

December 7, 2005

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER